IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

ALPHARMA, INC.	)	
	)	
Plaintiff,	)	Case No. 1:08CV00050
	)	
v.	)	**OPINION AND ORDER**
	)	
PURDUE PHARMA L.P.,	)	By: James P. Jones
	)	Chief United States District Judge
Defendant.	)	

Mark T. Hurt, Abingdon, Virginia, and Thomas G. Slater, Jr., Hunton & Williams LLP, Richmond, Virginia, Roger L. Tate and Robert M. Schulman, Hunton & Williams LLP, Washington, D.C., and David A. Kelly, Hunton & Williams LLP, Atlanta, Georgia, for Plaintiff; Wm. W. Eskridge and Wade W. Massie, Penn, Stuart & Eskridge, Abingdon, Virginia, and Gerald Sobel, Aaron Stiefel, and David S. Copeland, Kaye Scholer LLP, New York, New York, for Defendant.

In this patent case, I will deny the defendant's motion to dismiss for lack of subject matter jurisdiction or, alternatively, to transfer venue.

I

The plaintiff, Alpharma Inc., has developed a new prescription drug and hopes to bring it to market soon. To clear its path, it asks this court to declare several of the defendant's patents invalid and non-infringed. The defendant, Purdue Pharma L.P., moves to dismiss the case for lack of subject matter jurisdiction, Fed. R. Civ. P.

12(b)(1), or alternatively, to transfer it to the District of Connecticut, 28 U.S.C.A. § 1404(a) (West 2006).

The material before the court shows the following facts.[1]

Both parties manufacture and sell prescription pain medication. The plaintiff is incorporated in Delaware and has a principal place of business in Bridgewater, New Jersey, but it was recently acquired by King Pharmaceuticals, Inc. ("King"), which has headquarters in Bristol, Tennessee. The defendant is organized in Delaware as a limited partnership and has a principal place of business in Stamford, Connecticut.

The plaintiff has formulated a new drug called ALO-01. ALO-01 is an opioid based pain medicine which contains a substance called naltrexone. If ALO-01 is abused—that is, if it is crushed or chewed—naltrexone prevents the abuser from experiencing the euphoria caused by the opiate.

The defendant owns several patents in this field and aggressively enforces them. Knowing this, in January 2006, the plaintiff sought a "mutually beneficial business arrangement" with the defendant. (Compl. at 11.) For almost two years the parties held meetings to explore a collaborative project that involved the plaintiff's

[1] During oral argument, the parties agreed that I do not need to decide any issue of contested fact in order to resolve the present motions.

naltrexone technology. They signed a Confidential Disclosure Agreement ("CDA") to protect proprietary information and later expanded it.

During a meeting held on September 14, 2007, a representative of the defendant "stated that [the plaintiff] must be aware of [the defendant's] 'extensive intellectual property rights' in the field of abuse-resistant opioid formulations." (*Id.* at 13.) A representative of the plaintiff replied that it "was aware of [the defendant's] patents, but that based on its internal analysis of those patents, it believed it had the freedom to practice in this area." (*Id.*) A high-level officer of the defendant who was present responded by "stating his company's position that its patents were broad enough to encompass [the plaintiff's] naltrexone sequestering technology, and that it would be 'necessary to let the lawyers work [the dispute] out.'" (*Id.*)

On September 24, 2007, the parties met once more and then exchanged a series of emails. In one sent by the defendant to the plaintiff on October 9, 2007, the defendant stated that it "would provide [the plaintiff] with an 'updated response in the next couple of days following further discussions with [its] management.'" (*Id.* at 14.) The defendant also "offered to arrange for [its] VP & Chief IP Counsel to be available to [the plaintiff's] patent counsel if it would be helpful to [the plaintiff's] understanding" of the defendant's intellectual property. (*Id.*) No further collaboration occurred.

Approval of ALO-01 by the United States Food and Drug Administration ("FDA") is still pending. The plaintiff expected it by December 30, 2008, but a recent change in the FDA's Risk Evaluation and Mitigation Strategy of opioid drugs has delayed the process.[2] Nonetheless, the plaintiff has continued to develop ALO-01. It has produced commercial quantities of the drug and has assembled a marketing and sales team. As a result, the plaintiff has invested approximately $40 million in its success.

I must decide whether there is a justiciable case or controversy between the parties to maintain subject matter jurisdiction and whether the District of Connecticut is a substantially more convenient forum to hear the case. These issues have been briefed and argued, and are now ripe for decision.

II

In light of all the circumstances, I find a justiciable controversy between the parties, and that the District of Connecticut is not a substantially more convenient forum. Therefore, I will deny the present motions.

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[2] According to a recent letter from the FDA, the plaintiff must meet only "ministerial" requirements before the drug is approved. (Pl.'s Mem. in Opp'n to Def.'s Mot. to Dismiss or, Alternatively, to Transfer at 21 n.11.)

A

The plaintiff brings suit under the Declaratory Judgment Act, 28 U.S.C.A. § 2201(a) (West 2006) ("DJA"), which states in pertinent part that

> [i]n a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

I must initially determine whether the circumstances here present an "actual controversy," and therefore support subject matter jurisdiction. *Id.* If jurisdiction exists, I have discretion to exercise or withhold it. *See id.*

Whether there is an "actual controversy" under the DJA depends on whether the case is justiciable under Article III of the Constitution. *See MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126 (2007). Under Article III, federal courts have subject matter jurisdiction over only cases and controversies. *Id.*

In *MedImmune,* the Supreme Court revisited the case and controversy requirement as it relates to the DJA, and held that a patent licensee need not continue to pay royalties under a license agreement in order to seek a declaratory judgment of noninfringement, invalidity, and unenforceability against a patent holder. *Id.* at 137. Precedent required only

> that the dispute be definite and concrete, touching the legal relations of parties having adverse legal interests; and that it be real and substantial and admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.

Id. at 127 (internal quotes and citation omitted). That is, Article III requires that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Id.* (internal quotes omitted). Simply put, the plaintiff must show that there is a substantial controversy between the parties that is (1) definite and concrete and (2) sufficiently immediate and real.[3] *See id.*

Against this backdrop the defendant moves to dismiss for lack of subject matter jurisdiction. The defendant contends that nothing in the Complaint illustrates a

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[3] Before *MedImmune*, the Federal Circuit applied a two-prong test to evaluate subject matter jurisdiction. *See SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1379 (Fed. Cir. 2007). It first asked whether the conduct of the patentee had created a reasonable apprehension of an infringement suit on behalf of the declaratory judgment plaintiff, and then considered whether the declaratory judgment plaintiff had conducted infringing activity or had prepared to do so. *Id.* Previously determinative, this narrow two-part inquiry is now only part of an expansive all-of-the-circumstances test. *See MedImmune*, 549 U.S. at 132 n.11 (explaining how the reasonable apprehension of suit test contradicted, conflicted, or was in tension with precedent that evaluated Article III subject matter jurisdiction); *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1336 (Fed. Cir. 2008) (explaining that the reasonable apprehension of suit test is still relevant, though not dispositive); *Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 880 (Fed. Cir. 2008) (same as to the second prong).

dispute between the parties that is (1) definite and concrete or (2) sufficiently immediate and real. I disagree.

MedImmune involved a license dispute, but its principles have been interpreted to apply to conduct that occurs before an agreement is reached as well. The Federal Circuit has explained that

> [i]n the context of conduct prior to the existence of a license, declaratory judgment jurisdiction generally will not arise merely on the basis that a party learns of the existence of a patent owned by another or even perceives such a patent to pose a risk of infringement, without some affirmative act by the patentee. But Article III jurisdiction may be met where the patentee takes a position that puts the declaratory judgment plaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do. . . . [W]here a patentee asserts rights under a patent based on certain identified ongoing or planned activity of another party, and where that party contends that it has the right to engage in the accused activity without license, [jurisdiction will lie].

SanDisk Corp., 480 F.3d at 1380-81.

During the meeting held on September 14, 2007, and in response to a remark by the defendant that it had extensive property rights in the field of abuse-resistant pain medication, the plaintiff related that it had studied the defendant's patents and concluded that "it had the freedom to practice in this area." (Compl. at 13.) The defendant opined that its patents encompassed the plaintiff's naltrexone technology,

and that "it would be necessary to let the lawyers work [the dispute] out." *Id.* (internal quotes omitted.)

These comments alone evince a dispute definite and concrete in nature. The defendant asserted that its patents cover the plaintiff's naltrexone technology. The plaintiff disagreed. In the email it sent to the plaintiff, the defendant offered to have its Chief IP Counsel explain the extent of its patents. There would be no need for the lawyers to confer if the defendant did not believe that this difference in opinion did not touch the legal interests of the parties.

The defendant argues that its statements were not a threat of litigation. They occurred in a friendly business setting, and did not amount to "a detailed presentation which identified, on an element-by-element basis," the manner in which it believed the plaintiff's products infringed the defendant's patents. *SanDisk Corp.*, 480 F.3d at 1382.

Nevermind that the defendant did not explicitly threaten the plaintiff with litigation. In fact, in *SanDisk*, the defendant told the plaintiff that it would *not* sue, and that did not eliminate the justiciable controversy. *See id.* at 1382-83. All that *MedImmune* and its progeny require is an assertion of rights by the defendant which "puts theplaintiff in the position of either pursuing arguably illegal behavior or abandoning that which he claims a right to do . . . ." *Id.* at 1381. Here, the plaintiff

must either continue to produce a drug that is potentially encompassed by the defendant's patents or reluctantly forgo the drug's development.

The defendant maintains that it has not placed the plaintiff in such an untenable position, and points to the September 24, 2007 meeting in which the plaintiff agreed to an expanded CDA, the plaintiff's continued production of commercial quantities of ALO-01, and the plaintiff's marketing and sales activity since the alleged dispute. The defendant misses the point. That the plaintiff does not yield to the defendant's position does not make this case any less justiciable. Rather, it is justiciable because without a declaration of its rights, the plaintiff will continue to operate on legally uncertain grounds.

The plaintiff's uncertainty is all the more reasonable in light of the defendant's aggressive litigation strategy in similar cases. The Complaint describes several instances in which the defendant sued other drug manufacturers for infringement of its controlled-release opioid patents. Most relevant is the defendant's Citizen Petition filed with the FDA to oppose approval of Remoxy, a drug that appears similar in nature to ALO-01 and that is co-developed by Pain Therapeutics, Inc. and King, the company that recently acquired the plaintiff. This history is by no means determinative, but it is at least relevant in an analysis which must consider all the circumstances.

The defendant has failed to note anything indeterminate about this dispute. The plaintiff has identified those patents which it believes will allegedly impede the marketing and sale of ALO-01. The marketing and sale of ALO-01 is the potentially infringing activity. The facts here are not hypothetical.

Rather, they present a dispute which is sufficiently immediate and real.

For a controversy to qualify as "immediate" within the contours of subject matter jurisdiction, "there must be a showing of meaningful preparation for making or using [a] product." *Cat Tech LLC*, 528 F.3d at 881 (internal quotes and citation omitted). "[A] party need not have engaged in the actual manufacture or sale of a potentially infringing product . . . [,]" but "the greater the length of time before potentially infringing activity is expected to occur, the more likely the case lacks the requisite immediacy." *Id.* (internal quotes and citation omitted).

Here, the plaintiff has produced commercial quantities of ALO-01 and submitted a New Drug Application to the FDA. Although it cannot guarantee FDA approval on any particular date, the plaintiff has only ministerial requirements to satisfy before the drug is approved. It has trained marketing and sales teams and has

invested approximately $40 million in ALO-01. These facts demonstrate that the dispute between the plaintiff and defendant is sufficiently immediate.[4]

The controversy here is also sufficiently "real." A patent dispute is real "to the extent to which the technology in question is substantially fixed as opposed to fluid and indeterminate at the time declaratory relief is sought." *Cat Tech LLC*, 528 F.3d at 882 (internal quotes and citation omitted). It follows that "the greater the variability of the subject of a declaratory-judgment suit, particularly as to its potentially infringing features, the greater the chance that the court's judgment will be purely advisory, detached from the eventual, actual content of that subject—in short, detached from eventual reality." *Id.* (internal quotes and alteration omitted).

Neither the plaintiff nor the defendant suggest that the technology behind ALO-01 will change, even after FDA approval. The plaintiff has already produced commercial quantities of ALO-01, and that assures the drug will remain in its current form. The defendant has not suggested to the contrary.

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[4] *Compare Cat Tech LLC*, 528 F.3d at 881-82 (immediacy requirement satisfied where the plaintiff could not have taken any further steps toward manufacturing or selling the products at issue) *with Benitec Austl., Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1346 (Fed. Cir. 2007) (no immediacy where a party who had planned to engage in human gene-therapy treatment had not yet filed an NDA with the FDA).

This case presents a definite and concrete controversy that is real and immediate. Accordingly, I have discretion to entertain it. I must consider "whether resolving the case serves the objectives for which the [DJA] was created[,]" *id.* at 883, and I believe it does.

A plaintiff should not be forced to "'bet the farm, or . . . risk treble damages . . . before seeking a declaration of its actively contested legal rights.'" *Id.* (quoting *MedImmune*, 549 U.S. at 134). Without a declaration of its rights (or lack thereof), the plaintiff will be forced to either accrue potential liability in its development of ALO-01 or abandon its success. This choice "is precisely the type of 'dilemma that it was the very purpose of the [DJA] to ameliorate' . . . ." *Id.* (quoting *MedImmune*, 549 U.S. at 129).

The defendant argues that the exercise of subject matter jurisdiction here will inhibit any future discussion of patent rights between competitors, regardless of the setting in which it occurs. It views the discussions between the parties as nothing more than a collaborative business endeavor. In this light, to consider the extent of the defendant's patents would help determine whether those patents would protect a co-developed product.

This concern that *MedImmune* and *SanDisk* restrict a patentee's ability to negotiate the coverage of its intellectual property rights has not gone unnoticed. *See*

SanDisk, 480 F.3d at 1385 (Bryson, J., concurring) (stating that under the new legal standard, there is "no practical stopping point short of allowing declaratory judgment actions in virtually any case in which [a potential licensee] elects to dispute the need for a license and then to sue the patentee."). But it is not an argument to preclude subject matter jurisdiction here. Whatever the merits of *MedImmune* and *SanDisk*, those cases must inform my decision.

Because I find that there is a justiciable controversy, and because I believe that to entertain this case would serve the purpose of the DJA, I will deny the defendant's Motion to Dismiss for Lack of Subject Matter Jurisdiction.

B

The defendant has alternatively moved to transfer this case to the District of Connecticut under 28 U.S.C.A. § 1404(a), arguing that it is a substantially more convenient forum than the Western District of Virginia. Again, I disagree.

The movant bears the burden of showing that a transfer is proper. Relevant factors include the plaintiff's choice of venue, convenience to the witnesses and parties, and the interests of justice. The plaintiff's choice of forum should rarely be disturbed unless the balance is strongly in favor of the defendant. *See Gen. Creation LLC v. Leapfrog Enters., Inc.*, 192 F.Supp. 2d 503, 504-05 (W.D. Va. 2002).

A plaintiff's choice of forum deserves substantial weight, except when "(1) the plaintiff chooses a foreign forum, and (2) the chosen venue has little connection to the cause of action." *Id.* at 505. During oral argument, the defendant conceded that this court could be considered as the plaintiff's home district, in light of its acquisition by King, which has headquarters in nearby Bristol, Tennessee.[5] Accordingly, for the defendant to satisfy its burden that a transfer is proper, it must show that venue here is overwhelmingly inconvenient. *See id.*

The convenience of the parties and witnesses factor does not favor either side. Both parties have offices in the Northeast, but the plaintiff is owned by a company headquartered in nearby Bristol. The defendant anticipates that it will present testimony from witnesses who live in the Northeast. The plaintiff also intends to call witnesses who live in the Northeast, but they have expressed their willingness to travel. The plaintiff anticipates that at least some material evidence will be in Bristol.

The interest of justice factor is somewhat neutral as well. This court presided over the widely-publicized criminal convictions of a sister company of the defendant and its executives, *see United States v. Purdue Frederick Co.*, 495 F. Supp. 2d 569 (W.D. Va. 2007), and that may suggest the plaintiff is forum shopping. But I give

[5] King's headquarters are located approximately seventeen miles from this courthouse.

that notion less weight since the defendant concedes that this district qualifies as the plaintiff's home district. Moreover, in comparison to the District of Connecticut, a speedier disposition is more likely here because of our less congested docket.

The plaintiff's choice of forum deserves substantial weight and the convenience of the parties and witnesses and the interest of justice factors are neutral. Therefore, I find that the defendant has failed to show that the District of Connecticut is substantially more convenient than this court. Accordingly, the defendant's Motion to Transfer will be denied.

III

For the foregoing reasons, it is **ORDERED** that the defendant's Motion to Dismiss for Lack of Subject Matter Jurisdiction or, Alternatively, to Transfer to the District of Connecticut is DENIED.

ENTER: July 9, 2009

/s/ JAMES P. JONES
Chief United States District Judge